10/500157

Rec'd PCT/PTO 04 AUG 2004

PCT Application
PCT/JP2002/013557

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 140429-952	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/JP02/13557	International filing date (*day/month/year*) 25 December 2002 (25.12.02)	Priority date (*day/month/year*) 26 December 2001 (26.12.01)
International Patent Classification (IPC) or national classification and IPC C07D 487/04, A61K 31/55, A61P 29/00, 37/08		
Applicant	MEIJI SEIKA KAISHA, LTD.	

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 12 May 2003 (12.05.03)	Date of completion of this report 28 August 2003 (28.08.2003)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP02/13557

I. Basis of the report

1. With regard to the **elements** of the international application:*

☒ the international application as originally filed

☐ the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the claims:

pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the drawings:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP02/13557

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 8

because:

☒ the said international application, or the said claims Nos. 8 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

(see supplemental)

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 8 .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III. 1.

Claim 8 pertains to methods for treatment of the human body by therapy, and thus relates to subject matter which does not require international preliminary examination by this International Preliminary Examining Authority.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP 02/13557

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-7, 9	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-7, 9	NO
Industrial applicability (IA)	Claims	1-7, 9	YES
	Claims		NO

2. Citations and explanations

Document 1: EP 1026167 A (Meiji Seika Kaisha Ltd.), 9 August 2000

Document 2: US 6124281 A (Zeneca Limited), 26 September 2000

[1] The inventions set forth in claims 1-7 and 9 do not involve an inventive step in the light of documents 1 and 2 above, cited in the international search report.

The crystals described in claims 1-3 differ from the 2-(1-isopropoxycarbonyloxy-2-methylpropyl)-7,8-dimethoxy-4(5H),10-dioxo-2H-1,2,3-triazolo[4,5-c][1]benzoazepine disclosed in document 1 in that the former present data such as the x-ray diffraction data and the purity thereof, whereas the latter does not present such data (see document 1, page 13, paragraph [0080], pages 19-20, paragraphs [0118]-[0123], and page 37, Example 20, etc.).

However, obtaining a pure crystalline form of a compound having a useful action is conventional practice in the art, and document 1 also mentions that this compound can be purified by conventional recrystallization. Therefore, a person skilled in the art could easily try applying methylene chloride and an alcohol, used for the recrystallization of azolo-benzazepines (see document 2, columns 36-42, general

procedure, example 46-50, etc.) to this compound disclosed in document 1 in order to produce a compound with a specified crystalline form.

Moreover, the effects offered by the crystalline material in the inventions in the present application are common effects of crystallization such as purity and stability, and cannot be considered to be specially marked compared with the effects offered by the compound disclosed in document 1.

Procedures such as powder x-ray diffraction and melting point determination are also conventionally carried out in the art after producing crystals.

Therefore, the inventions set forth in claims 1-7 and 9 do not involve an inventive step.